

**LAW 10 February 2020, n. 10**

**Regulations on the disposition of one's own body and post-mortem tissues for study, training and scientific research.**

**(20G00024)**

*(GU n.55 of 4-3-2020)*

Existing at: 19-03-2020

The Chamber of Deputies and the Senate of the Republic have approved;

THE PRESIDENT OF THE REPUBLIC

Promulgate the following law:

**Art.1**

Object

1. This law lays down rules regarding the disposition of body and tissues for the purpose of study, training and scientific research by subjects who have expressed in life their consent according to the modalities established by Article 3.
2. The use of the human body or post-mortem tissues is informed by the principles of solidarity and proportionality and governed according to modalities' such as to ensure respect for the human body.
3. The body and tissues of subjects whose death has been established by certificate issued by the competent bodies, according to the law of 29 December 1993, n. 578, and subsequent implementing decrees can be used for study, training and scientific research.
4. After death and the declaration of death, the body of the deceased must remain in the morgue for at least twenty-four hours before being used for study, training, and scientific purposes.

NOTES

Warning:

The text of the notes published in this document has been prepared by the competent administration, pursuant to art. 10, paragraphs 2 and 3, of the single text of the provisions on the promulgation of laws, on the issuing of decrees by the President of the Republic and on the official publications of the Italian Republic, approved by Presidential Decree no. 1092 of 28 December 1985, for the sole purpose of facilitating the reading of the provisions of the law that have been modified or to which reference is made. The value and effectiveness of the legislative acts transcribed herein remain unchanged.

**Art. 2**

Promotion of information

1. The Ministry of Health promotes, with due respect for a free and informed choice, information initiatives aimed at raising awareness among citizens of the provisions of this law, using the resources available under current legislation for the implementation of institutional communication projects.

2. The regions and local health authorities shall adopt, in accordance with the regulations set forth in Article 8, initiatives aimed at:
  - a) disseminate among the doctors of general medicine and pediatricians of free choice and among doctors of public and private health facilities and health care professionals, knowledge of the provisions of this law;
  - b) disseminate among citizens, through appropriate advertising at the municipal administrations and also through voluntary organizations, correct information on the use of the human body and post-mortem tissues for the purposes of study, medical training and scientific research.

### **Art. 3**

#### Manifestation of consent

1. The act of disposing of one's own body or post-mortem tissues occurs through a declaration of consent to the use of the same drawn up in the forms provided for in Article 4, paragraph 6, of Law 22 December 2017, n. 219. The declaration is delivered to the health company to which it belongs, which is obliged to preserve it and transmit telematically the contents to the database referred to in paragraph 418 of Article 1 of Law 27 December 2017, n. 205.
2. The settlor, in the declaration referred to in paragraph 1, indicates also a person of his trust, hereinafter referred to as "trustee", who is responsible for communicating the existence of this specific consent to the doctor who ascertains the death, as identified by the regulation referred to in the decree of the President of the Republic 10 September 1990, n. 285. In the same declaration the settlor can indicate a replacement for the trustee who will perform the role in the event of death or supervening incapacity of these, where they occurred before the settlor's death, as well as in the case of objective impossibility for the trustee to promptly carry out tasks provided for by this law.
3. The trustee and any substitute must be persons of age and capable of understanding and willing. Acceptance of the appointment by the trustee and the substitute takes place through the signing of the declaration of consent. To the trustee and to the substitute a copy of the declaration of consent is issued. The trustee and substitute may revoke their acceptance in any time with a written deed, which is communicated to the settlor.
4. The appointment of the trustee, as well as of his substitute, can be revoked by the settler at any time with the same modalities' foreseen for the appointment and without obligation of motivation.
5. The person giving consent may revoke it at any time in the modalities prescribed by paragraph 1. The revocation must be communicated to the health care authorities to which it belongs, which will transmit it to the data bank referred to in paragraph 1. In cases where reasons of emergency and urgency prevented to proceed to the revocation of consent already manifested with the forms referred to in paragraph 1, it can be expressed with a verbal statement collected or videotaped by a doctor, with the assistance of two witnesses.
6. For minors' consent to the use of the body or post-mortem tissues must be expressed in the forms referred to in paragraph 1 by both parents exercising parental responsibility or by guardians or foster parents under the law of May 4, 1983, n. 184. The revocation referred to in paragraph 5 shall also be expressed by only one of the persons referred to in the first sentence of this paragraph.

### **Art. 4**

#### Reference Centers

1. The Minister of Health, in agreement with the Minister of of education, university and research, after agreement in the Permanent Conference for relations between the State, the regions and the autonomous provinces of Trento and Bolzano, identifies the university facilities, the hospital companies of high specialty and the Institutes for hospitalization and care of scientific character (IRCCS) to be used

as reference centers for the preservation and the use of the bodies of the deceased for the purposes referred to in this law.

2. The activities of the centers of reference referred to in paragraph 1 that require the use of the body of a corpse or its organs or tissues must be in accordance with the scientific research projects for which the independent ethics committee territorially competent identified pursuant to Legislative Decree no. 211 of June 24, 2003, of Article 12, paragraphs 10 and 11, of Decree-Law no. 158 of September 13, 2012, n. 158, converted, with amendments, by the law of November 8, 2012, no. 189, and of article 2 of law no. 3 of January 11, 2018, has issued a favorable opinion. The surgical training activity, where in line with the educational paths of the reference center authorized, does not require the opinion of the ethics committee but only the authorization by the health management of the structure of belonging.

#### **Art. 5**

Establishment of a national list of reference centers for the conservation and use of the bodies of the deceased

1. The Ministry of Health has established the National List of the reference centers identified in accordance with article 4 for the conservation and utilization of the bodies of deceased persons.
2. The List, which can be consulted on the internet site of the Ministry of Health is promptly updated in order to allow the doctor who ascertains the death to identify the competent reference center for the territory, to which he/she gives notice of the death of the person who has given notice
3. The reference center, having acquired through the database data referred to in Article 3, the proof of consent, provides the withdrawal of the body of the deceased, giving notice to the company health authority to which the disposer belongs.
4. The implementation of the provisions envisaged by this article shall be carried out within the scope of the human, instrumental and financial resources provided for by current legislation and, in any case, without new or greater burdens for the public finance.

#### **Art. 6**

Return of the body of the deceased

1. The reference centers identified pursuant to Article 4, which have in taken delivery for study, training and scientific research the body of a subject referred to in Article 1, are required to return the body to the family in a dignified condition within twelve months from the date of delivery.
2. The costs for the transport of the body from the moment of death until its return, the expenses related to burial, as well as the costs for any cremation shall be borne by the reference centers identified in accordance with Article 4, which provide within the resources allocated to research projects.

#### **Art. 7**

Regulations of donations of money for the purposes of study, training and research

1. The use of the human body, parts thereof, or postmortem tissue may not be for profit.
2. Any donations of money made by private individuals for the purpose of study, training and scientific research through the use of the bodies of the deceased or resulting from the finalization of research projects are intended for the management of reference centers identified under Article 4.

#### **Art. 8**

Regulations for implementation

1. Within three months from the date of entry into force of this law, by regulation to be adopted in accordance with article 17, paragraph 1, letter b), of law no. 400 of 23 August 1988, on the proposal of the Minister of Health, in agreement with the Minister of the Interior and the Minister of Education, Universities

and Research, following an agreement at the Permanent Conference for relations between the State, the regions and the autonomous provinces of Trento and Bolzano, the following is provided for a:

- a) establish the procedures and time limits, in any case not exceeding twelve months, for the conservation, for the request, for the transport, for the use and for the return of the body of the deceased in decent conditions to the family by the centers of references referred to in Article 4, providing that you can proceed with the burial of the bodies of the deceased for whom the family of family does not request restitution, as well as the modalities for communications between the civil registrar and the reference centers;
- b) indicate the causes for excluding the use of the bodies of the deceased persons for the purposes set forth in this Act;
- c) provide for the linkage with the civil status system regulated by the civil status governed by the regulations set forth in presidential decree President of the Republic no. 396 of November 3, 2000;
- d) dictate the discipline of the initiatives envisaged by art.2, paragraph 2.

#### **Art. 9**

##### Financial Provisions

The implementation of this law shall not give rise to new or increased burdens on the public finances. The public administrations public administrations involved in its implementation shall provide for it with the sole human, financial and instrumental resources available under current legislation.

#### **Art. 10**

##### Abrogation

1. Article 32 of the Consolidated Text of the Laws on Higher Education as per Royal Decree 1592 of 31 August 1933, is repealed.
2. This Law, bearing the seal of the State, shall be included in the official collection of the normative acts of the Italian Republic. It is obligatory for anyone to observe it and have it observed as a law of the State.

Given in Rome, on February 10, 2020.

MATTARELLA

### **LAW 19 September 2012, n. 167**

**Rules to allow partial transplantation of lung, pancreas and intestine between living people. (12G0184)**

(GU n.227 of 28-9-2012)

Effective on: 29-9-2012

The Chamber of Deputies and the Senate of the Republic have approved;

THE PRESIDENT OF THE REPUBLIC

Promulgate the following law:

**Art. 1**

Partial lung, pancreas and intestinal transplant

1. Notwithstanding the prohibition referred to in article 5 of the civil code, is admitted to have free parts of the lung, pancreas and intestine for the exclusive purpose of transplantation between living people.
2. For the purposes referred to in paragraph 1, insofar as they are compatible, the provisions of law no. 458, and the regulation referred to in the decree of the Minister of Health April 16, 2010, n. 116.
3. The implementation of this law is carried out within the limits of human, financial and instrumental resources available under current legislation and, in any case, without new or greater charges for the public finance.

**Art. 2**

Entry into force

1. This law enters into force on the day following that of its publication in the Official Gazette
2. This law, bearing the seal of the State, will be included in the Official Collection of Regulatory Acts of the Italian Republic. It is mandatory for anyone who is responsible to observe it and do it observe as state law.

Given in Rome, September 19, 2012

NAPOLITANO

Monti, President of the Council of Ministers

Seen, the Keeper of Seals: Severino

**LAW 16 December 1999, n. 483****Rules for allowing partial liver transplantation.**

(Official Gazette 297 of 20-12-1999)

Effective on: 21-12-1999

The Chamber of Deputies and the Senate of the Republic have

approved;

THE PRESIDENT OF THE REPUBLIC Promulgates

the following law:

**Art. 1.**

Partial liver transplant

1. Notwithstanding the prohibition referred to in Article 5 of the Civil Code, it is permitted to dispose of liver parts free of charge for the purpose exclusive of transplantation between living people.
2. For the purposes referred to in paragraph 1, the provisions of law no. 458.

**Art. 2.**

Entry into force

1. This law enters into force on the day following that of its publication in the Official Gazette.
2. This law, bearing the seal of the State, will be included in the Official Collection of Regulatory Acts of the Italian Republic. It is mandatory for anyone who is responsible to observe it and do it observe as state law.

Given in Rome, December 16, 1999

CIAMPI

D'Alema, Prime Minister

of Ministers

Seen, the Keeper of Seals: Diliberto

**LAW 26 June 1967, n. 458 Kidney**

**Transplant between living persons.**

(GU n.160 of 27-6-1967)

Effective on: 12-7-1967

The Chamber of Deputies and the Senate of the Republic have approved;

THE PRESIDENT OF THE REPUBLIC

PROMOTE the following law:

**Art. 1.**

1. Notwithstanding the prohibition referred to in Article 5 of the Civil Code, it is allowed to dispose of the kidney free of charge for the purpose of transplantation between living people.
2. The derogation is allowed to parents, children, siblings or non-Germans of the patient who are of age, as long as they are complied with the procedures provided for by this law. Only in the event that the patient does not have the relatives referred to in the previous paragraph or none of them is suitable or available, the derogation can also be allowed for other relatives and for donors strangers.

**Art. 2.**

1. The act of disposition and destination of the kidney in favour of a specific patient is received by the magistrate of the place where he resides the donor or the authorized transplant institute is located.
2. The donation of a kidney may be authorized, provided that the donor has reached the age of majority, is in possession of the ability to understand and will, is aware of the limitations of kidney transplant therapy between living beings and is aware of the personal consequences that his sacrifice entails. The magistrate, having ascertained the existence of the conditions referred to in the previous paragraph and also ascertained that the donor was determined at the time of donating a kidney freely and spontaneously, draws up in writing the related statements.

3. The act, which is free of charge and does not tolerate the affixing of conditions or other accessory determinations of will, is always revocable until the time of surgery and does not give rise to any rights of the donor towards the recipient. The magistrate, having ascertained the existence of the technical judgment in favour of the removal and transplantation of the kidney contained in the medical report referred to in the following article, may grant, by decree to be issued within three days, the no impediment for the execution of the transplant.
4. Otherwise and within the same term, he declares, by decree motivated, their refusal.
5. Against this decree it is possible to lodge a complaint with an appeal to the Court, which pronounces in the Council Chamber.
6. All acts of the proceedings before the praetor and the court are not subject to the provisions of the tax law of register and stamp.

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**2. Art. 3.**

3. The removal and transplantation of the kidney can be carried out in centres for organ transplants, in university institutes, and in hospitals which are also considered suitable for scientific research. The aforementioned Centres, Institutes and Hospitals must have health professionals who are particularly qualified for medical, surgical, biological and must be authorized by the Minister for Health, having heard the opinion of the Higher Council of Health and, for universities, also the opinion of the 1st section of the Council higher education institution.
4. The director of the Institute who intends to perform a kidney transplant, having completed and checked all the necessary investigations, gathers his collaborators in the medical college with the participation of a trusted doctor of the donor and draws up a special report certifying the suitability of the donor also under the aspect of histocompatibility, as well as the existence of the clinical indication al transplant in the patient.
5. This final report with a favourable technical judgment, is sent to the provincial doctor, who, having ascertained compliance with the conditions of the previous paragraph, transmits it, within 24 hours, to the magistrate for the issue of the authorization for the execution of the transplant, referred to in Article 2.

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**7. Art. 4.**

8. The kidney transplant legitimately taken and intended for a specific patient cannot take place without his consent or in the absence of a state of necessity.

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**10. Art. 5.**

11. For the kidney removal surgery, the donor is allowed to enjoy the benefits provided by the laws in force for self-employed or subordinate workers in a state of infirmity; it is also insured against the immediate and future risks inherent in the intervention

12. surgery and the impairment suffered.

14.

**15. Art. 6.**

16. Any private agreement that provides for compensation in money or other utility in favour of the donor, to induce him to disposition and destination is null and void.

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**18. Art. 7.**

19. Anyone who carries out the work of mediation in the donation of a kidney.

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**21. Art. 8.**

22. The Minister for Health, in agreement with the Minister for Labour and social security, will issue the regulations for the implementation of the this law within six months of its entry into force.

23. This law, bearing the seal of the State, will be included in the Official Collection of laws and decrees of the Italian Republic. It is mandatory for anyone who is responsible to observe it and do it observe as state law.

24.

25. Given in Rome, June 26, 1967

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27. SARAGAT
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29. MORO - MARIOTTI - REAL
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31. Seen, the Keeper of Seals: REAL